

LOG OF MEETING

SUBJECT: Lidocaine/Dibucaine

DATE OF MEETING: May 25, 1994

PLACE: CPSC Headquarters, Bethesda, MD

LOG ENTRY SOURCE: Suzanne Barone, Ph.D., Pharmacologist, HSPS

COMMISSION REPRESENTATIVE: See attached list.

NON-COMMISSION REPRESENTATIVE: See attached list.

SUMMARY OF MEETING:

The CPSC requested that the NDMA task force and other interested parties meet to discuss Commission staff and industry activities concerning lidocaine/dibucaine since the proposal was published on August 4, 1992. The staff indicated that 10 comments were received and that a package was being prepared to present to the Commission with the option to finalize the rule. The comments did not contain information that would change the staff recommendation. One option for the Commission is to finalize the temporary exemption for manufacturers having difficulty finding packaging that would comply.

The industry representatives reiterated that the OTC products were not associated with deaths and that child-resistant tubes are not currently available on the market. The staff indicated that a child-resistant tube is technically feasible but has not been tested with children or seniors. The product manufacturers using aerosols and pumps also had concerns about the availability of senior effective child-resistant packaging for these products. Industry representatives indicated that the market volume of these products is not sufficient to support the development of new child-resistant packaging for these products.

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application CRSC CPSC-HSP5 THEWEST CO CPSC/OGC NDMA PSL PSL SF NDM4 Schering-Plough MKES INC CIBA CONSUMER CIBA Consumer Pharm. CIBA COUSUMER PHARM. CPSC/CERM CPSC/EPHA CPSC/HS CASC/ECON PDC Reports "The Tan Cheet" 301-657-9833

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AGENDA

LIDOCAINE/DIBUCAINE May 25, 1994 1:30

- I. Introductions
- II. Discussion of Commission Staff Activities
 - A. Analysis of comments
 - B. Option for Commission to finalize rule
- III. Industry activities since submission of comments
- IV. General Discussion